510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY

A. 510(k) Number:
k040508

B. Analyte:
Magnesium

C. Type of Test:
Quantitative

D. Applicant:
Clinical Data, Inc

E. Proprietary and Established Names:
Vitalab Magnesium Reagent

F. Regulatory Information:

1. Regulation section:
   21 CFR 862.1495
2. Classification:
   Class I
3. Product Code:
   JGJ
4. Panel:
   75

G. Intended Use:

1. Indication(s) for use:
   The Vitalab Magnesium Reagent Kit is intended for use with the Vitalab Selectra E Analyzer as a system for the quantitative determination of magnesium in serum and plasma. Magnesium results may be used for the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).
2. Special condition for use statement(s):
   Prescription use
3. Special instrument Requirements:
   The Vitalab Magnesium Reagent is intended to be used with the Vitalab Selectra E Chemistry Analyzer.

H. Device Description:
The Vitalab Magnesium Reagent and the Vitalab Selectra E Analyzer are used as a system for the quantitative analysis of magnesium in serum and plasma. The Vitalab Magnesium Reagent is

supplied as a single part liquid-stable reagent and is intended to be calibrated with the Vitalab Serum Calibrator. Magnesium concentrations are calculated from the endpoint absorbance at 505 nm.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Roche Magnesium Reagent Kit, product 11489330
2. Predicate K number(s):
   K983416
3. Comparison with predicate

Similarities		
Item	**Vitalab Magnesium**	**Roche Magnesium**
Intended Use	Similar	Similar
Type of test	Quantitative	Quantitative
Principle	Chelation of magnesium by xylidyl blue to produce a colored dye with EGTA to remove calcium interference	Similar
Measurement	Chemical endpoint at approximately 500 nm (505 nm)	Similar
Differences		
Item	**Vitalab Magnesium**	**Roche Magnesium**
Sample type	Serum, plasma	Serum, plasma and urine
Analytical range	0.1 to 5.0 mg/dL	0.07 to 4.86 mg/dL

I. Standard/Guidance Document Referenced (if applicable):

NCCLS EP3-T, NCCLS EP7-P

J. Test Principle:

The Vitalab Magnesium Reagent determines magnesium through chelation by xylidyl blue producing a colored complex. The resulting increase in absorbance at 505 nm is proportional to the magnesium concentration of the sample.

K. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. ***Precision/Reproducibility****:*

   Precision is demonstrated by the replicate assay of commercially available control serum. Each sample is assayed in triplicate twice in twenty runs over 10 days using the Vitalab Magnesium Reagent on a Selectra E Analyzer. Precision statistics, calculated analogous to the method described in NCCLS Guideline EP3-T, are shown below.

Precision of Magnesium Recoveries in mg/dL

		Within Run			Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	60	1.2	0.03	2.2%	0.4	3.2%
Serum 2	60	2.2	0.02	0.8%	0.3	1.1%
Serum 3	60	3.3	0.02	0.7%	0.3	1.0%

b. ***Linearity/assay reportable range****:*

The linear range of the assay is from 0.1 to 5.0 mg/dL. Ten standards with values ranging from 0.0 to 6.0 mg/dL are prepared to span the linear range of the application by dissolving magnesium metal in dilute acid. These standards and the acid matrix are assayed on a Vitalab Selectra E in ascending order over five independently calibrated analytical runs. Standard recoveries are compared to standard concentrations by least squares linear regression through the origin. A residual statistic is calculated for each standard as the difference between the mean recovery and its predicted value from the regression statistics. The maximum residual is 0.2 mg/dL magnesium indicating linearity throughout the linear range.

c. Traceability (controls, calibrators, or method):

Calibrator set points are traceable to NIST SRM 929.

d. Detection limit:

Normal saline is assayed thirty times in a single analytical run. The detection limit is calculated as the mean plus two standard deviations of the results. The observed mean and standard deviation are both 0.0 mg/dL. The detection limit of the assay is 0.1 mg/dL magnesium, which is the round-off error of the assay.

e. Analytical specificity:

Potential interference from icterus (bilirubin), hemolysis (hemoglobin) and lipemia (triglycerides) is determined in three separate studies. In each study, a serum pool with approximately normal magnesium levels is prepared from individual patient specimens and is divided into two aliquots. One aliquot is spiked with the potential interfering substance. The other aliquot is diluted with normal saline, if necessary, to mimic the dilution the spiked pool. These aliquots are then blended to prepare test pools with the interferant concentrations listed below. The red blood cell (RBC) hemolysate, which is used to spike the high pool for the hemolysis test, is prepared from at least five patient specimens according to the Osmotic Shock Procedure described in NCCLS Document EP7-P, Volume 6 No.13.

Interfering Substance	Levels tested
Ditaurobilirubin	8, 16, 24, 32, 40 mg/dL (as bilirubin)
RBC hemolysate	40, 80, 120, 160, 200 mg/dL (as hemoglobin)
Intralipid, 20%	400, 800, 1,200, 1,600 and 2,000 mg/dL (as triglycerides)

Each set of original and spiked pools are assayed in an alternating order 9 and 6 times respectively in a single analytical run. Differences in recoveries between the original and spiked pools are reported with t-statistics. Statistically significant differences greater than 0.3 mg/dL are reported on the package insert.

Bilirubin and red blood cell hemolysate do not affect recoveries.
The addition of Intralipid to triglycerides concentrations of 1,600 and 2,000 mg/dL triglycerides increased results by 0.2 and 0.4 mg/dL respectively.

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. Method comparison with predicate device:
Random specimens from individual anonymous adult patients are collected from local clinical labs. These unaltered samples are supplemented with additional specimens with elevated magnesium levels to yield a total of 60 serum and 60 heparinized plasma specimens. These specimens are randomly assorted into groups of 15 serum and 15 plasma specimens each. One group of serum and plasma specimens are assayed in each of four runs using the Vitalab Selectra Magnesium Application and the Roche Magnesium Reagent on the Hitachi 704 after calibrating each reagent with its required calibrator.

The serum results, plasma results and the combined results for both specimen types are each compared by Deming regression assuming equal variances between methods. Two serum results were identified by residual analysis and excluded from the following comparisons because the Roche/Hitachi results were not reproducible. Regression statistics are given below.

Serum Correlation

	Value	95% Confidence Interval
Intercept	0.32 mg/dL	0.27 to 0.37 mg/dL
Slope	0.876	0.855 to 0.897
$s_{y.x}$	0.03 mg/dL	
n	58	
range	1.5 to 5.2 mg/dL	

Plasma Correlation

	Value	95% Confidence Interval
Intercept	0.19 mg/dL	0.06 to 0.31 mg/dL
Slope	0.953	0.898 to 0.1.009
$s_{y.x}$	0.04 mg/dL	
n	60	
range	1.5 to 2.8 mg/dL	

Combined Correlation

	Value	95% Confidence Interval
Intercept	0.31 mg/dL	0.26 to 0.36 mg/dL
Slope	0.889	0.867 to 0.912
$s_{y.x}$	0.04 mg/dL	
n	118	

range 1.5 to 5.2 mg/dL

Where x = Predicate Results
y = Selectra Results

b. Matrix comparison:

Serum and plasma specimens are individually compared to the predicate method by Deming regression. Although the slope estimates for the two specimen types appear to differ, combining the two regression equations to solve for the expected bias between serum and plasma results yields:

Bias = (Serum Results – Plasma Results) = 0.136 mg/dL – 0.077(x).

This equation predicts biases of +0.06 mg/dL at 1.0 mg/dL and -0.13 mg/dL at 3.5 mg/dL magnesium. These predicted differences are insignificant when compared to the quoted reference range of 1.6 to 2.6 mg/dL and the round off error of +/- 0.1 mg/dL.

3. Clinical studies:
   - *a.* ***Clinical sensitivity:***
     Not applicable
   - *b.* ***Clinical specificity:***
     Not applicable
   - *c.* ***Other clinical supportive data (when a and b are not applicable):***
     Not applicable
4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range:
   Reference ranges are established in the literature and quoted from Tietz Textbook of Clinical Chemistry, Third Edition, Burtis and Ashwood, editors, W. B. Saunders Company (1999). The expected values are from 1.6 to 2.6 mg/dL.

L. Conclusion:

Based upon a Third Party Review of the information provided in this 510(k), this device is substantially equivalent to devices regulated by 862.1495, photometric method, magnesium; Class I.